

Docket No. 4614-4000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jiandong DING et al.

Group Art Unit: TBA

Serial No.: 10/762,029

Examiner: TBA

Filed: January 20, 2004

For: A THERMOSENSITIVE AND BIODEGRADABLE MICROGEL AND A METHOD
FOR THE PREPARATION THEREOF

INFORMATION DISCLOSURE STATEMENT

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:


This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed _____.

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☒ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
 - ☐ 37 C.F.R. §1.97(b)(4), before the mailing date of a first office action after the filing of an RCE under §1.114.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500., Order No. 4614-4000. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: February 11, 2004

By: 
Maria C.H. Lin
Registration No. 29,323

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☒ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
 - ☐ 37 C.F.R. §1.97(b)(4), before the mailing date of a first office action after the filing of an RCE under §1.114.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500., Order No. 4614-4000. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: February 11, 2004

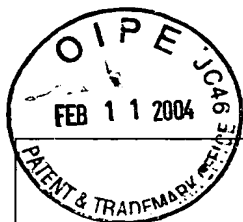
By:



Maria C.H. Lin
Registration No. 29,323

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile



FORM PTO-1449

INFORMATION DISCLOSURE CITATION

Attorney Docket:
4614-4000Serial No.:
10/762,029Applicant:
Jiandong DING et al.Filing Date:
January 20, 2004Group Art Unit:
TBA

U.S. PATENT DOCUMENTS

Examiner Initial	Patent Number	Publication Date	Name	Class	Sub-Class	Filing Date
	4,352,883	10/1982	Lim	435	178	
	4,716,203	12/1987	Casey et al.	525	408	
	5,986,043	11/1999	Hubbell et al.	528	354	
	6,030,634	2/2000	Wu et al.	424	423	
	6,060,582	9/2000	Hubbell et al.	528	354	
	6,129,761	10/2000	Hubbell et al.	623	11	
	6,306,922	10/2003	Hubbell et al.	522	71	
	6,541,033	4/2003	Shah	424	486	
	0,099,709	5/2003	Shah et al.	424	469	

FOREIGN PATENT DOCUMENTS

Examiner Initial	Patent Number	Publication Date	Country	Class	Sub-Class	Translation
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No

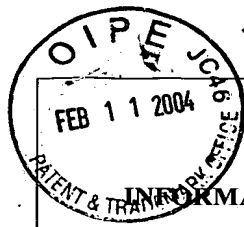
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, etc.)

	Baldwin S P., Saltzman W M., "Materials for Protein Delivery in Tissue Engineering," Adv. Drug. Deliv. Rev. 33: 71-86 (1998)
	Blanco D., Alonso M J., "Protein Encapsulation and Release from Poly(lactide-co-glycolide) Microspheres: Effect of the Protein and Polymer Properties and of the Co-encapsulation of Surfactants," Eur. J.Pharm. Biopharm. 45: 285-294 (1998)
	Bromberg L E., Ron E S., "Temperature-responsive Gels and Thermogelling Polymeric Matrices for Protein and Peptide Delivery," Adv. Drug. Deliv. Rev. 31: 197-221 (1998)
	Cho K Y., Choi S H., Kim C H., Nam Y S., Park T G., Park J K., "Protein Release Microparticles Based on the Blend of Poly(d,l-lactic-co-glycolic acid) and Oligo-ethylene glycol Grafted Poly(l-lactide)," J. Control. Release 76: 275-284 (2001)
	Cohen S., Yoshioka T., Lucarelli M., Hwang L H., Langer R., "Controlled Delivery Systems for Proteins Based on Poly(lactic/glycolic acid) Microspheres," Pharm. Res. 8: 713-720 (1991)
	Fu J., Zhou R X., Fan C L., "Studies on the Syntheses and Properties of Poly(ester-anhydride)s for DDS," Chemical Journal of Chinese Universities 19(5): 813-816 (1998)

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609.
Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to Applicant.



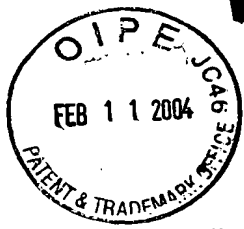
FORM PTO-1449

INFORMATION DISCLOSURE CITATION

Attorney Docket:
4614-4000Serial No.:
10/762,029Applicant:
Jiandong DING et al.Filing Date:
January 20, 2004Group Art Unit:
TBA**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, etc.)**

	Fu J., Zhou R X., Fan C L., "Studies on the Syntheses and Drug Release Properties of Polyanhydrides Containing Phosphonoformic (or Acetic) Acid Ethyl Ester in the Main Chain," Chemical Journal of Chinese Universities 18(10): 1706-1710 (1997)
	Jain R A., Rhodes C T., Railkar A M., Malick A W., Shal N H., "Controlled Release of Drugs from Injectable in Situ Formed Biodegradable PLGA Microspheres: Effect of Various Formulation Variables," Eur. J. Pharm. Biopharm. 50: 257-262 (2000)
	Jeong B., Bae Y H., Lee D S., Kim S W., "Biodegradable Block Copolymers as Injectable Drug-delivery Systems," Nature 388: 860-862 (1997)
	Langer R., "Drug Delivery and Targeting," Nature 392: 5-10 (1998)
	Lanza R P., Langer R., Vacanti J., "Principles of Tissue Engineering (2nd Ed.), Academic Press, New York, 2000
	Li M X., Zhuo R X., Qu F Q., "Synthesis and Characterization of Novel Biodegradable Poly(ester amide) with Ether Linkage in the Backbone Chain," J. Polym. Sci. part A: Polym. Chem. 40(24): 4550-4555 (2002)
	Sawhney A S., Hubbell J A., "Rapidly Degraded Teropolymers of dl-lactide, glycolide, and ε-caprolactone with Increased Hydrophilicity and Copolymerization with Polyethers," J Biomed. Mater. Res. 24(10): 1397-1411 (1990)
	Sawhney A S., Pathak C P., Hubbell J A., "Bioerodible Hydrogels Based on Photopolymerized Poly(ethyleneglycol)-co-poly(α-hydroxy acid) Diacrylate Macromers," Macromolecules 26: 581-587 (1993)
	Singh M., Shirley B., Bajwa K., Samara E., Hora M., O'Hagan D., "Controlled Release of Recombinant Insulin-like Growth Factor from a Novel Formulation of Polylactide-co-glycolide Microparticles," J. Control. Release 70: 21-28 (2001)
	Wu C., Zhou S Q., "Thermodynamically Stable Globule State of a Single Poly(N-isopropylacrylamide) Chain in Water," Macromolecules 28(15): 5388-5390 (1995)
	Wu C., Zhou S Q., "Internal Motions of Both Poly(N-isopropylacrylamide) Linear Chains and Spherical Microgel Particles in Water," Macromolecules 29(5):1574-1578 (1996)
	Yasuhiko T., "The Importance of Drug Delivery Systems in Tissue Engineering," Pharmaceutical Science & Technology Today 3: 80-89 (2000)
	Zentner G M., Rath R., Shin C., McRea J C., Seo M H., Oh H., Rhee B G., Mestecky J., Moldoveanu Z., Morgan M., and Weitman S., "Biodegradable Block Copolymers for Delivery of Proteins and Water-insoluble Drugs," J. Control. Release 72: 203-215 (2001)
	Zhuo R X., Li W., "Preparation and Characterization of Macroporous Poly(N-isopropylacrylamide) Hydrogels for the Controlled Release of Proteins," J. Polym. Sci. part A: Polym. Chem. 41(1): 152-159 (2003)
	Zhu Z X., Xiong C D., Zhang L L., Yuan M L., Deng X M., "Preparation of Biodegradable Polylactide-co-poly(ethylene glycol) Copolymer by Lactide Reacted Poly(ethylene glycol)", Eur. Polym. J. 35: 1821-1828 (1999)

Examiner	Date Considered
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	



02-12-04

Docket No. 4614-4000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jiandong DING et al.

Group Art Unit: TBA

Serial No.: 10/762,029

Examiner: TBA

Filed: January 20, 2004

For: A THERMOSENSITIVE AND BIODEGRADABLE MICROGEL AND A METHOD FOR THE PREPARATION THEREOF

EXPRESS MAIL CERTIFICATE

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Express Mail Label No.: EV 245 493 990US

Date of Deposit: February 11, 2004

I hereby certify that the following attached paper(s) and/or fee

1. Information Disclosure Statement;
2. Form PTO 1449;
3. 30 cited references;
4. Return postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Shen-Frattura

(Typed or printed name of person mailing paper(s) and/or fee)

(Signature of person mailing paper(s) and/or fee)

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile



Docket No. 4614-4000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jiandong DING et al.

Group Art Unit: TBA

Serial No.: 10/762,029

Examiner: TBA

Filed: January 20, 2004

For: A THERMOSENSITIVE AND BIODEGRADABLE MICROGEL AND A
METHOD FOR THE PREPARATION THEREOF

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

List of References

U. S. PATENT DOCUMENTS

- | | | | | |
|----|-----------|---------|----------------|---------|
| 1. | 4,352,883 | 10/1982 | Lim | 435/178 |
| 2. | 4,716,203 | 12/1987 | Casey et al. | 525/408 |
| 3. | 5,986,043 | 11/1999 | Hubbell et al. | 528/354 |
| 4. | 6,030,634 | 2/2000 | Wu et al. | 424/423 |
| 5. | 6,060,582 | 9/2000 | Hubbell et al. | 528/354 |
| 6. | 6,129,761 | 10/2000 | Hubbell et al. | 623/11 |
| 7. | 6,306,922 | 10/2003 | Hubbell et al. | 522/71 |
| 8. | 6,541,033 | 4/2003 | Shah | 424/486 |
| 9. | 0,099,709 | 5/2003 | Shah et al. | 424/469 |

OTHER PUBLICATIONS

10. Baldwin S P., Saltzman W M., "Materials for Protein Delivery in Tissue Engineering," *Adv. Drug. Deliv. Rev.* 33: 71-86 (1998)
11. Blanco D., Alonso M J., "Protein Encapsulation and Release from Poly(lactide-co-glycolide) Microspheres: Effect of the Protein and Polymer Properties and of the Co-encapsulation of Surfactants," *Eur. J.Pharm. Biopharm.* 45: 285-294 (1998)

12. Bromberg L E., Ron E S., "Temperature-responsive Gels and Thermogelling Polymeric Matrices for Protein and Peptide Delivery," *Adv. Drug. Deliv. Rev.* 31: 197-221 (1998)
13. Cho K Y., Choi S H., Kim C H., Nam Y S., Park T G., Park J K., "Protein Release Microparticles Based on the Blend of Poly(d,l-lactic-co-glycolic acid) and Oligo-ethylene glycol Grafted Poly(l-lactide)," *J. Control. Release* 76: 275-284 (2001)
14. Cohen S., Yoshioka T., Lucarelli M., Hwang L H., Langer R., "Controlled Delivery Systems for Proteins Based on Poly(lactic/glycolic acid) Microspheres," *Pharm. Res.* 8: 713-720 (1991)
15. Fu J., Zhou R X., Fan C L., "Studies on the Syntheses and Properties of Poly(ester-anhydride)s for DDS," *Chemical Journal of Chinese Universities* 19(5): 813-816 (1998)
16. Fu J., Zhou R X., Fan C L., "Studies on the Syntheses and Drug Release Properties of Polyanhydrides Containing Phosphonoformic (or Acetic) Acid Ethyl Ester in the Main Chain," *Chemical Journal of Chinese Universities* 18(10): 1706-1710 (1997)
17. Jain R A., Rhodes C T., Railkar A M., Malick A W., Shal N H., "Controlled Release of Drugs from Injectable in Situ Formed Biodegradable PLGA Microspheres: Effect of Various Formulation Variables," *Eur. J. Pharm. Biopharm.* 50: 257-262 (2000)
18. Jeong B., Bae Y H., Lee D S., Kim S W., "Biodegradable Block Copolymers as Injectable Drug-delivery Systems," *Nature* 388: 860-862 (1997)
19. Langer R., "Drug Delivery and Targeting," *Nature* 392: 5-10 (1998)
20. Lanza R P., Langer R., Vacanti J., "Principles of Tissue Engineering (2nd Ed.), Academic Press, New York, 2000
21. Li M X., Zhuo R X., Qu F Q., "Synthesis and Characterization of Novel Biodegradable Poly(ester amide) with Ether Linkage in the Backbone Chain," *J. Polym. Sci. part A: Polym. Chem.* 40(24): 4550-4555 (2002)
22. Sawhney A S., Hubbell J A., "Rapidly Degraded Teropolymers of dl-lactide, glycolide, and ϵ -caprolactone with Increased Hydrophilicity and Copolymerization with Polyethers," *J Biomed. Mater. Res.* 24(10): 1397-1411 (1990)
23. Sawhney A S., Pathak C P., Hubbell J A., "Bioerodible Hydrogels Based on Photopolymerized Poly(ethyleneglycol)-co-poly(α -hydroxy acid) Diacrylate Macromers," *Macromolecules* 26: 581-587 (1993)
24. Singh M., Shirley B., Bajwa K., Samara E., Hora M., O'Hagan D., "Controlled Release of Recombinant Insulin-like Growth Factor from a Novel Formulation of Polylactide-co-glycolide Microparticles," *J. Control. Release* 70: 21-28 (2001)
25. Wu C., Zhou S Q., "Thermodynamically Stable Globule State of a Single Poly(N-isopropylacrylamide) Chain in Water," *Macromolecules* 28(15): 5388-5390 (1995)
26. Wu C., Zhou S Q., "Internal Motions of Both Poly(N-isopropylacrylamide) Linear Chains and Spherical Microgel Particles in Water," *Macromolecules* 29(5):1574-1578 (1996)

27. Yasuhiko T., "The Importance of Drug Delivery Systems in Tissue Engineering," *Pharmaceutical Science & Technology Today* 3: 80-89 (2000)
28. Zentner G M., Rath R., Shin C., McRea J C., Seo M H., Oh H., Rhee B G., Mestecky J., Moldoveanu Z., Morgan M., and Weitman S., "Biodegradable Block Copolymers for Delivery of Proteins and Water-insoluble Drugs," *J. Control. Release* 72: 203-215 (2001)
29. Zhuo R X., Li W., "Preparation and Characterization of Macroporous Poly(N-isopropylacrylamide) Hydrogels for the Controlled Release of Proteins," *J. Polym. Sci. part A: Polym. Chem.* 41(1): 152-159 (2003)
30. Zhu Z X., Xiong C D., Zhang L L., Yuan M L., Deng X M., "Preparation of Biodegradable Polylactide-co-poly(ethylene glycol) Copolymer by Lactide Reacted Poly(ethylene glycol)", *Eur. Polym. J.* 35: 1821-1828 (1999)